

CONFIDENTIAL

**LASERLIGN II
PROCEDURE MANUAL**

Welcome to **Laserlign II**, a newly developed extramedullary method to align the Distal Femoral Resection for Total Knee arthroplasty without violating the intermedullary canal. This patent pending method uses a miniature high tech laser to triangulate the center of the femoral head without the need for an inter-operative X-ray.

By avoiding IM rods for alignment considerable morbidity will be spared your patient. Our studies using **Laserlign I**, an extramedullary alignment system in over 500 cases (several surgeons over the past 5 years) has shown marked improvement in the following: 1) 50% less blood loss rarely requiring transfusion. 2) Marked improvement in the patients sensorium and lethargy post surgery due to subacute fat embolism, well documented in several studies, allowing the patients to be discharged from the hospital, on the average, one day earlier. 3) Improved alignment > 90% within 1.5 degrees of optimal alignment.

Surgeons who have used the system appreciate the **Laser Ruler** that can be used throughout the case to confirm the Mechanical Axis allowing for interoperative adjustments.

The **Laserlign II** is actually more accurate than the **Laserlign I** system that required an x-ray to determine the center of the femoral head. It is intuitive and based on sound mechanical principles that leave no doubt that your analysis is correct. The laser gives the surgeon visual confirmation compared to other extramedullary systems that are based on faith that the mechanical principle is correct.

The Laserlign II system can be used with any commercial Total Knee System. The Laser keys on the Distal Femoral Resector therefore this vital instrument is included in our system. Since the Laser/Resector must be as flat as possible to the anterior femoral cortex several other instruments that prepare the distal femur for the Laser/resector are included as well. The other commercial systems pick up after the preliminary cut on the anterior femoral condyles and the **Laserlign II** resection of the distal femoral condyles.

The procedure includes a Laser that is set up over the femoral head on a platform that creates a **Laser Ruler**, i.e. the **Mechanical Axis**, for the surgeons to refer to throughout the case to make sure their alignment is correct. This is extremely gratifying to be able to confirm on the operating table that the alignment is correct.

STEP 1: THE SETUP

A) POSITION THE PATIENT ON THE OPERATIVE TABLE:

Apply the non-sterile **Operative Table Clamp** to the side rail of the operative table as far distally as it will go in the second section of the operative table. Be sure this is on the same side as the operative knee. As the patient is being positioned on the operative table use the non-sterile **Target Positioner** within the Operative Table Clamp so that when the patients hip is flexed to 90 degrees it just touches the horizontal arm of the Positioner. Move the patient up or down or if there is room cephalad move the clamp. This will insure that the Target will be correctly positioned over the patient's hip. Now prep the knee and drape in the usual fashion.

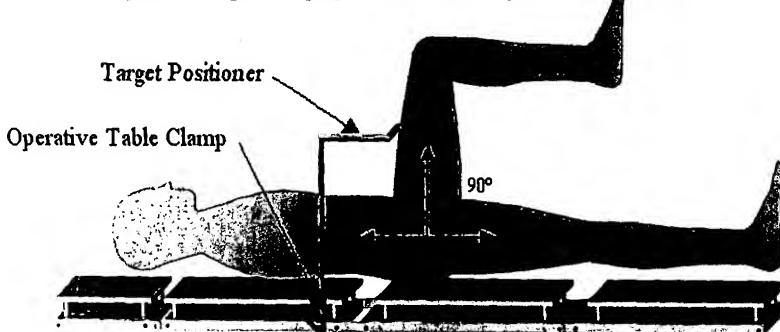


Fig. 1

B) APPLY THE LASER TARGET OVER THE HIP:

Apply the sterile **Target attachment arm** to the operative table through a small slit through the drapes into the operative table clamp. Cover the slit in the drapes with a towel and tightly towel clip. Hold the **Attachment Arm** rigid with the adjustment holes pointing to the patient's head while the nurse tightens the Attachment Arm into place into operative table clamp. Now apply the **Horizontal Bar** pointing distally to the Attachment Arm. Be sure the arm is flipped over to the correct side and tighten the adjustment screw when the arm is about **6 inches** above the patient's abdomen (you need the height to flex the knee). Now slide the **Laser Target** on the Horizontal Bar from the open end. Be sure the center of the target is facing distally. The actual center of the Femoral Head will be distal to the Hip Target leading edge by the bulk of the soft tissues on the anterior thigh.

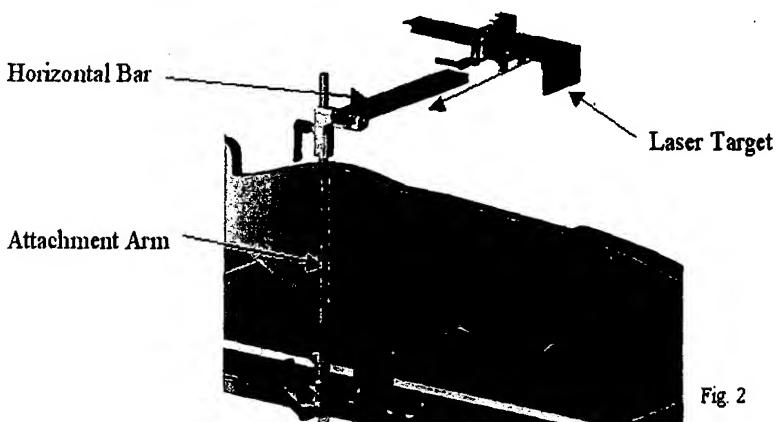


Fig. 2

C) ESTIMATE LOCATION OF THE FEMORAL HEAD

Adjust the Target's Bull's-eye transversely to be centered over the femoral head, approximately 2 inches medially to the anterior superior iliac spine (ASIS)(The lateral edge of the target will be directly over the ASIS). Pull the Laser Target distally about 2.5 inches from the closed position. The center of the target (Bull's-eye) will now be over the approximate center of the femoral head. It is vitally important that the leading edge of the target be pulled past the center of the femoral head by at least 2 inches to facilitate the triangulation process. If there is not enough adjustment in the target, move the operative table clamp distally. This moves the entire target distally, resulting in more adjustability.

For the triangulation process to work, you will need to be able to move the operative leg at least 10 to 15 degrees (in neutral rotation) in both adduction and abduction. In the rare case of ankylosis or significant contracture or the hip, another method of alignment must be used because the center of rotation will not be obtainable by laser triangulation.

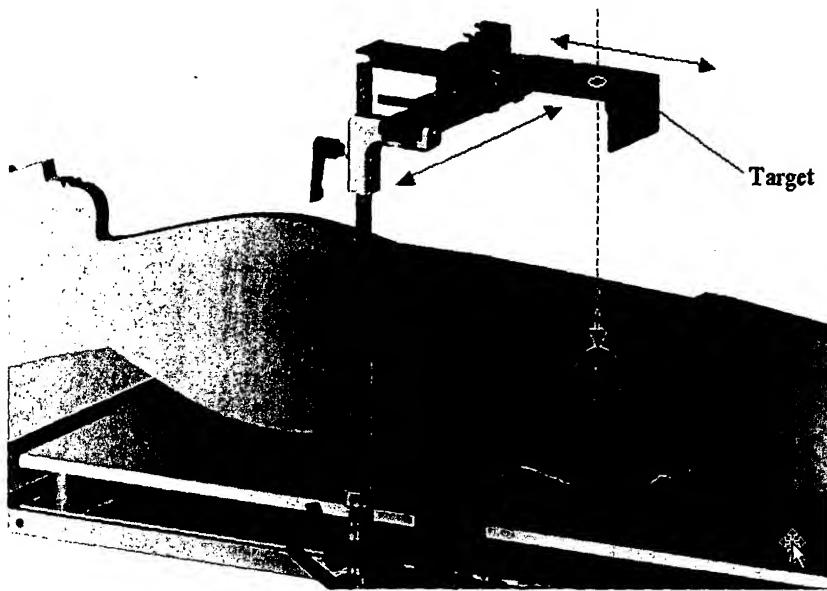


Fig. 3

The patient location and Laser Target setup are now complete.

Using the standard approach to total knee arthroplasty, direct your attention to the distal femur.

STEP 2: PREPARE THE DISTAL FEMUR

A) CENTRALIZE THE INTRACONDYLAR NOTCH

File the intracondylar notch with a **5/16 inch (.312) Rasp**. It is a vital importance to determine the exact center of the knee which, is usually, located slightly medial to the existing notch. Remove all the osteophytes and deepen the notch with the rasp. It is important that the subsequent V-Frame bottoms out on the adjacent femoral condyles and is not held proud by the V-Frame's Notch Guide that engages this filed recess.

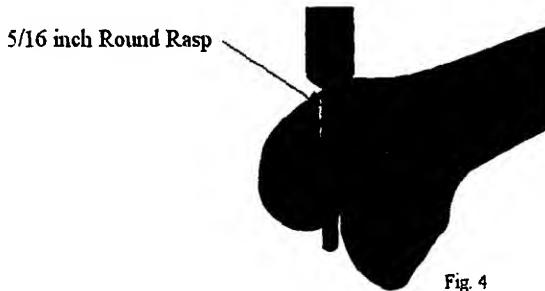


Fig. 4

B) CREATE FLAT PLANE ON ANTERIOR FEMORAL CORTEX

File the anterior intracondylar notch flush with the anterior femoral cortex with a **5/8 inch flat Rasp**. Aim 5-7 degrees medially, which is the direction of the femoral head. There is usually a 5-10 degree medial slope of the anterior femoral cortex so the file will take more bone off on the lateral side. The cutting guide will sit on this plane so make it as flat as possible.

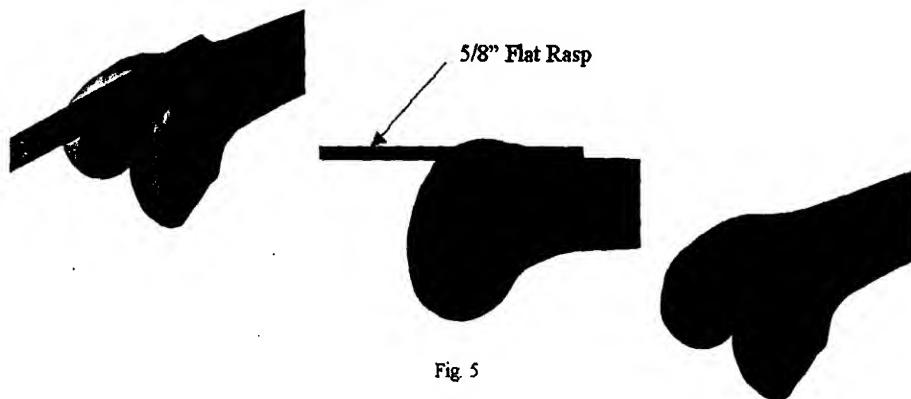


Fig. 5

C) REMOVE ANTERIOR FEMORAL CONDYLES

Use the **Anterior Condyle Resector Guide** flush on the filed plane in the intracondylar notch to resect the anterior femoral condyles with the saw flush with the top of the guide. This leaves 1/8 inch of anterior condylar bone above the filed central plane.

Anterior Condyle Resector Guide

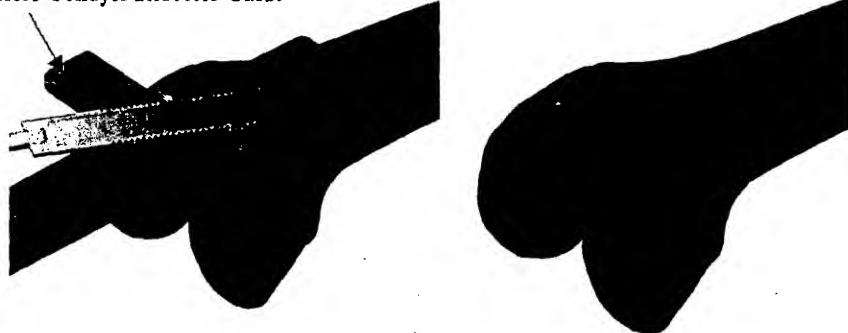


Fig. 6

STEP 3: APPLY HARDWARE TO DISTAL FEMUR

A) APPLY "V" FRAME TO DISTAL FEMUR

Apply the **V Frame** with the **Tongue** flush to the filed anterior femoral cortex. Hold the 1/4 inch **Notch Rod** tight into the intracondylar notch making sure the distal femoral condyles engage the **V Frame**. Pre-drill the outer cortices only, then screw cortical screws into at least two holes on each side. Make sure the **Tongue** is still flush with the anterior femoral cortex while affixing the V-Frame to bone.

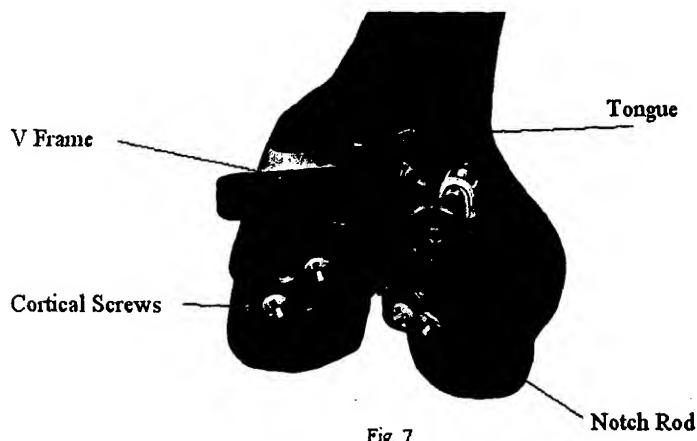


Fig. 7

B) APPLY DISTAL FEMORAL RESECTOR TO "V" FRAME

NOTE: Remove the Tongue before proceeding with this next step. Failure to do so will impede the resection of the distal femoral condyles.

Apply the **Distal Femoral Resector Guide** to the **V Frame** at the same time center the **Adjustment knob** pivot into its receptor on the resector guide. This locks the resector guide into rough alignment with the center of the femoral head. Be sure the resector is set to the 90-degree mark (resector indicator arm is flush with the anterior edge of the V-Frame).

Next apply the **Retractor Shield** into the square slot at the proximal end of the **Distal Femoral Resector Guide** and lock into place by pushing down and distally. This retractor shield will allow good visibility of the fixation holes on the proximal arm of the Distal Femoral Resector Guide.

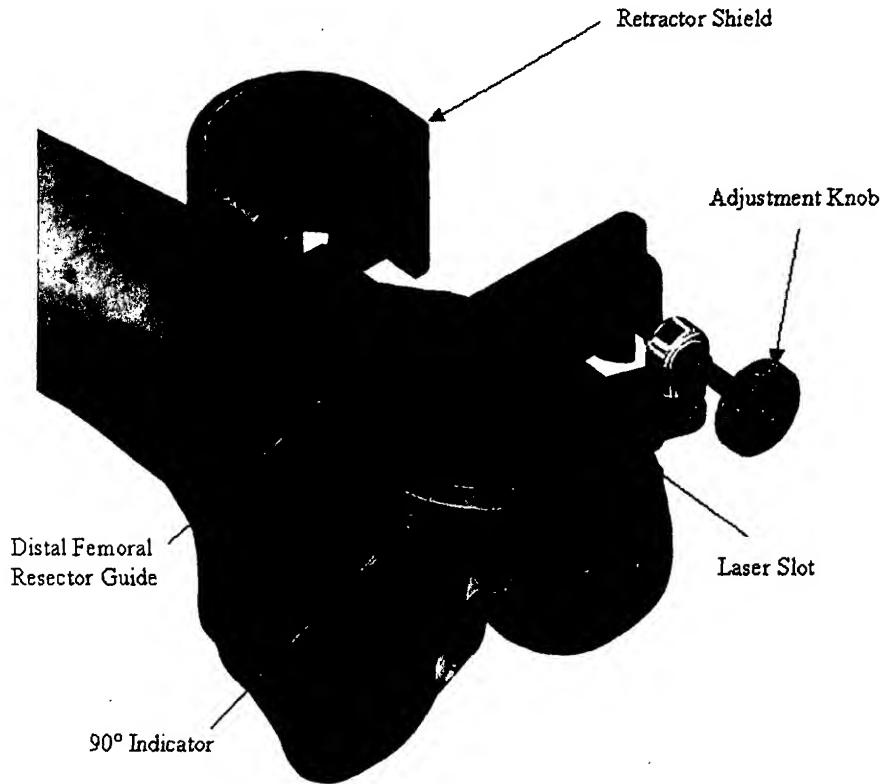
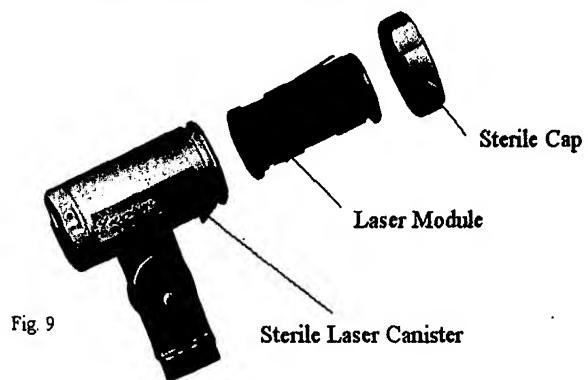


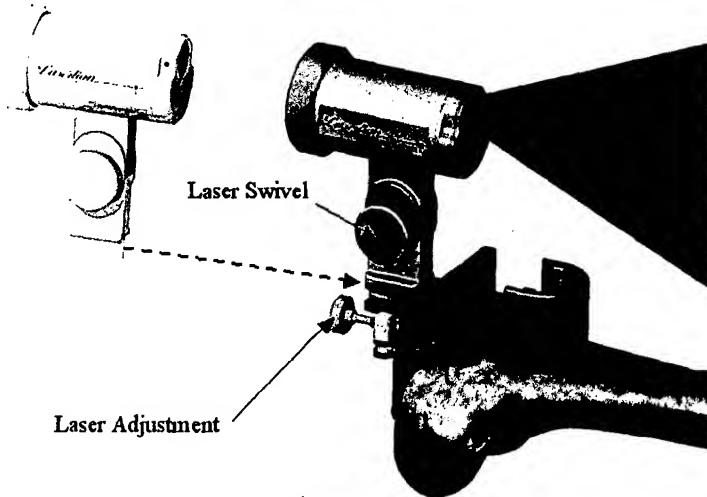
Fig. 8

STEP 4 LASER SETUP & ALIGNMENT OF THE LASER

The Laser Module used in this procedure cannot be sterilized! Steam sterilization would damage the delicate laser components. Therefore, the nurse inserts the non-sterile laser module into the Sterile Laser Canister. The groove on the laser module must be aligned with the rib on the laser canister. The laser automatically illuminates when inserted, and turns off when removed. The surgeon closes the canister with the sterile cap. The surgeon then inserts the self-centering alignment flange on the bottom of the canister into the tapered alignment groove on the Distal Femoral Resector Guide. The same Laser will later be moved to the Target mount for creating the Longitudinal Axis (Laser Ruler) to be used to check alignment throughout the case. The sterile canister is held in place by a built-in self-locking feature.



The Laser Module is now locked into alignment with the Distal Femoral Resector Guide and is located at the midpoint of the knee. What needs to be determined now is the center of the femoral head, so we can accurately locate the Mechanical Axis of the Femur.



ALIGNMENT OF THE LASER

First apply the Laser at the Knee, line up the knee laser to be co-linear by positioning the leg, and moving the Target in the transverse plane until the laser beam illuminate the centerline of the target. Be sure to hold the leg as straight as possible, parallel with the operating table. It is also very important to keep the laser line positioned vertically, keeping the beam parallel with the vertical markers on the Target. *Rotation of the knee will impair the accuracy of the laser beam. Therefore, it is important to always make sure the beam is parallel to the vertical lines on the front of the Target Vertical Adjustment whenever making a determination.*

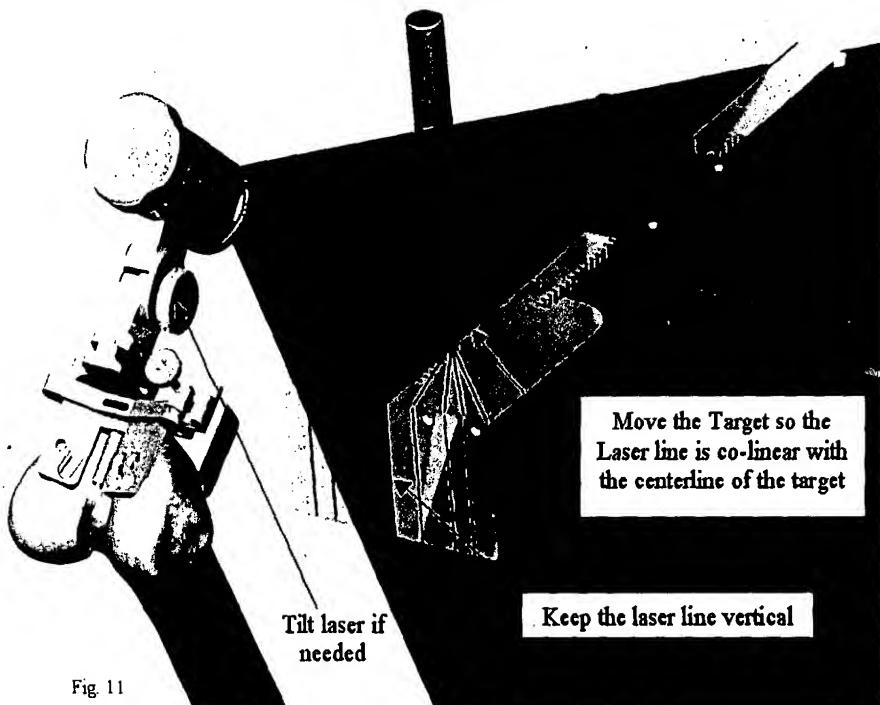


Fig. 11

A word of caution before starting the triangulating process: Occasionally, the laser beam will not illuminate the top of the target. This is likely in a patient with a fat thigh. In this case use the swivel mechanism on the side of the LASER to tilt the Laser beam upward until it shows on the top of the target. Also the entire target can be moved up for a flexed thigh hitting the underside of the target. Two people are needed, one to hold the leg parallel to the lines on the Target and the other to make the target adjustments.

STEP 5: LOCATING THE FEMORAL HEAD

FIRST: Determine the Longitudinal Axis of the Knee Laser

- a. Line up the Knee Laser with the centerline on the Target. This "preliminary" longitudinal axis will be within a few degrees of the actual because of the anatomical fit of the **V-Frame** in the femoral intercondylar notch. (Fig. 12)
- b. Swing the patients flexed leg laterally (**L**) to 30 degrees and hold in place. Make a small dot on the target centerline where it intersects the laser line. Label this dot **L**. (Fig. 12)
- c. Next, sweep the leg medially (**M**) to 30 degrees and hold in place. Make another small dot on the target centerline at the laser line intersection. Label this dot **M**. NOTE: If the points are coincident, skip ahead to Step 2. (Fig. 12)
- d. Move the Target longitudinally so the "Bulls-eye" is on the centerline of the more superior dot of the two beams. Use the targets built in ruler to count down from the present position. (Fig. 13)

****IMPORTANT:** When dot **L** is superior to the **M** dot, the Knee laser adjustment is medial. If dot **M** is superior to the **L** dot, Knee laser adjustment is made laterally.

- e. Carefully measure the distance between dot **L** and dot **M** with a ruler or by counting the number of 2mm lines on the built-in ruler results in a distance "e" (Figure 15) divide this distance by two. Draw a short midline transverse axis between the dots. (Figure 15)
- f. Using the same midline distance in mm (one-half of distance "e") make a "Corrective dot" in the direction of the correction on this midline. (Fig. 15)
- g. With the Knee Laser returned to centerline of the Target, dial the **ADJUSTMENT KNOB** on the **Distal Femoral Resector Guide** to a parallel position with the "Corrective Dot". This adjustment will correct the longitudinal axis of the Knee to the center of the femoral head. (Fig. 15 & 16)

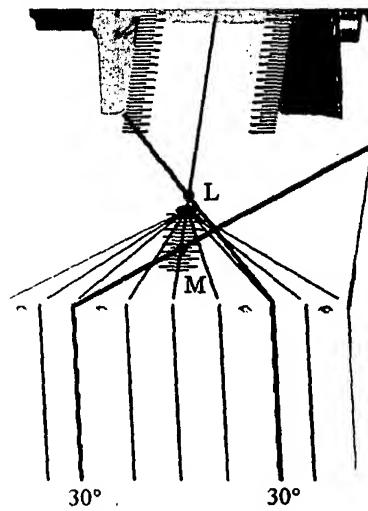


Fig. 12

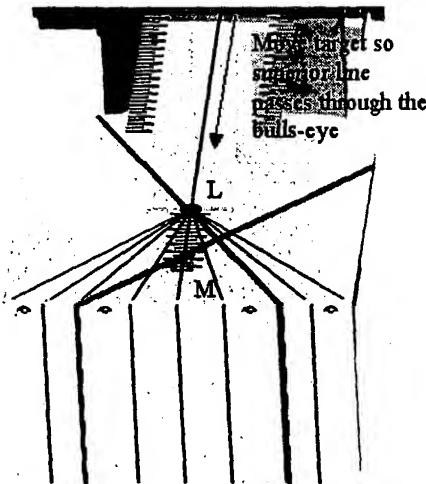


Fig. 13

Example of a typical adjustment for FIRST

- a) Make Knee Laser co-linear with Target Centerline by moving target transversely.
- b) Move the leg laterally 30 degrees, label location on center line with a dot marked L.
- c) Move the leg medially 30 degrees, label location on center line with a dot marked M.
- d) Move the Target longitudinally so the Bull's-eye is on the centerline of the more superior of the two marks.
- e) Measure distance between Dot L and Dot M. Take the midpoint (one-half the distance "e") and draw a short transverse axis line.
- f) Use the same midpoint distance on the short transverse axis line to make a "Corrective Dot" in the direction of the correction.
- g) Dial the ADJUSTMENT KNOB on the Knee Laser to a parallel position to the "Corrective Dot".

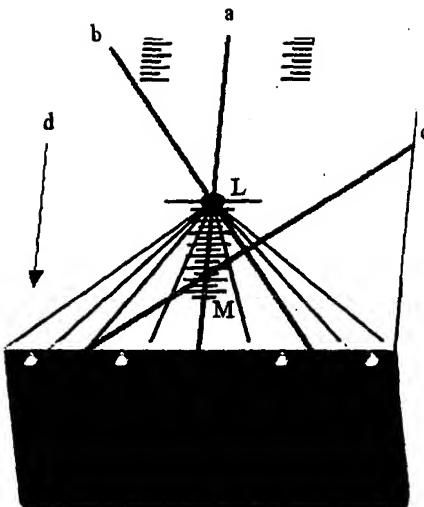


Fig. 14

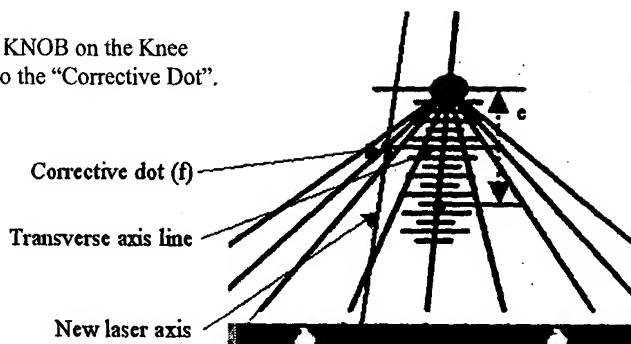


Fig. 15

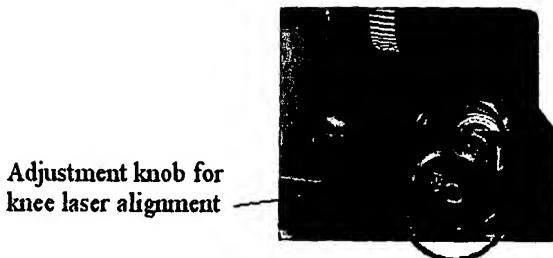


Fig. 16

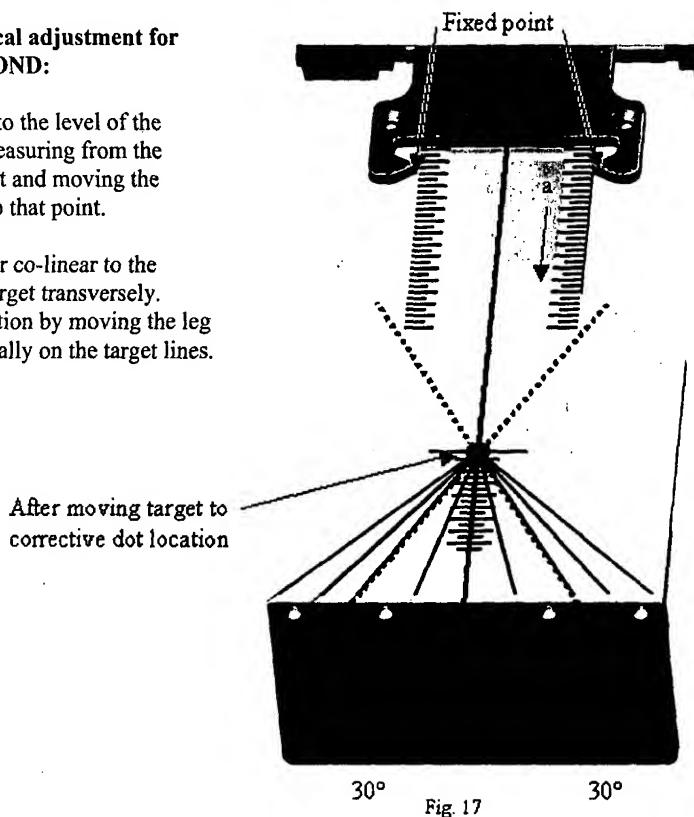
SECOND: Adjust the Longitudinal and Transverse Axis of Target to Knee Laser:

- a. Move the Target transverse axis (Bulls-eye) by pulling the Target longitudinally to the midpoint of the "Correction Dot". Measure this distance from a fixed position on the Target.
- b. Now make the **Knee Laser beam co-linear with the Target centerline by moving the target transversely** (Figure 11). There is only one position the Bulls-eye will line up with the medial and lateral radial lines for this patient, which is the exact center of the femoral head.. (Fig. 17)

Minor adjustments can be made here if you are a perfectionist by moving the Bulls-eye longitudinally and adjusting the knee laser Adjustment Knob to match the selected radial line. After making an Adjustment Knob change, be sure to always make the Knee laser is co-linear with the Targets centerline BY MOVING the Target transversely. If it is not lining up, do not panic, simply repeat the FIRST step from where your present position.

**Example of a typical adjustment for
SECOND:**

- a) Move the Bulls-eye to the level of the "Corrective Dot" by measuring from the fixed point on the target and moving the Target longitudinally to that point.
- b) Make the Knee Laser co-linear to the target by moving the target transversely. Test the Bulls-eye location by moving the leg both medially and laterally on the target lines.



THE BULLS-EYE OF THE LASER TARGET IS NOW POSITIONED DIRECTLY OVER THE CENTER OF THE FEMORAL HEAD, AND THE BEAM IS SHOWING THE LEG'S MECHANICAL AXIS.

Check the results by moving the Knee Laser beam medially and laterally keeping it parallel with the front of the target. It should transverse through the center of the Target Bulls-eye. Do not worry if it is slightly off the center of the Bulls-eye because the Laser is extremely sensitive. If you are within the **quarter inch circle** you will be accurate within a quarter of a degree of the actual center of the Femoral Head. Spending a lot of time for perfection is not worth it because it is rare to make the resection cuts that accurate. Later minor adjustments can be made with the Longitudinal Laser Line during the cementing process.

The knee laser is now removed and the distal femoral cut is made with the saw. Be sure to remove the cortical screws holding the V-Frame to the distal condyles before making this resection. The V-Frame itself can also be removed if loose. The laser is now moved to the Target Laser Mount to create the "Laser Ruler". (Fig. 18) The remainder of the knee arthroplasty is done in the conventional manner.

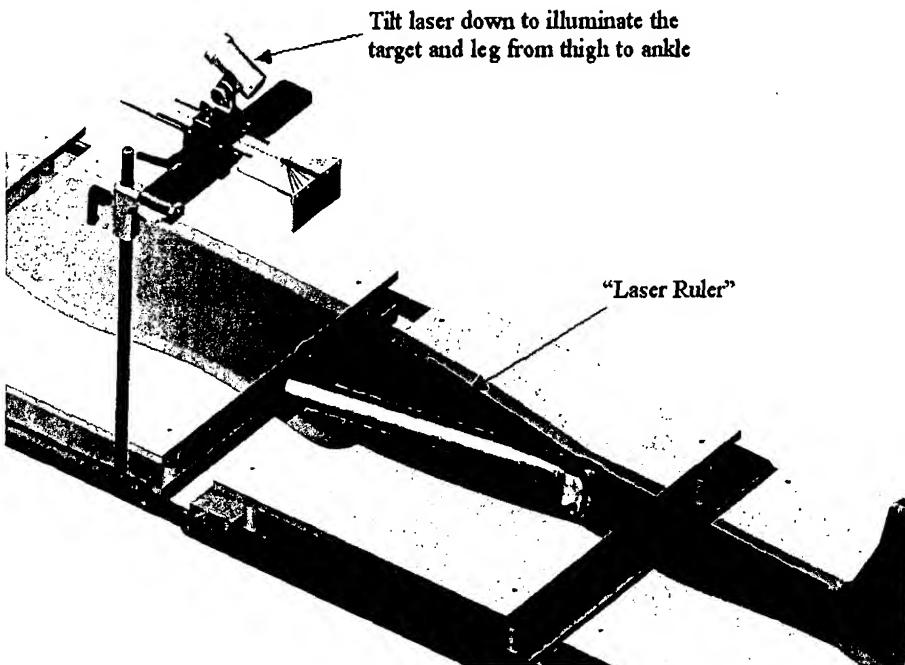


Fig. 18

VALUE OF THE LONGITUDINAL AXIS RULER:

Since the hip laser is centered on the femoral head the straight line this laser emits is the mechanical axis for this patient. Neutral alignment is when the laser passes through the center of the knee and the center of the ankle. Hold the leg parallel to this line to check your alignment after making all cuts with the trial components in place.

HELPFUL HINTS:

While aligning the leg on the Mechanical Axis laser-line watch out for external rotation errors. There is a tendency for the femur to externally rotate especially in heavier patients while resting on the operative table. About 10-15 degrees of rotation error can equal 1 degree of alignment error depending on the length of the patient's femur.

To avoid this error the surgeon should stand at the end of the operating table with one hand under the distal femur rotating the femur to neutral and pushing the trial components together with his belly. He then must align the laser beam on the center of the knee and ankle. Deviation of the laser beam from the center of the knee is the alignment error from neutral (mechanical axis).

For alignment errors less than one-degree (6-7mm) use bone cement to correct the error to neutral. For errors more than 1 degree (>7mm) be sure that rotation is not causing some of this error. Then check the tibial resection by re-applying the tibial resector and make sure this cut is perpendicular to the axis of the tibia. Tibial error is easily fixed by filing down the high side evenly. Femoral errors that cannot be filed will require re-applying the distal femoral cutting jigs. You now have an accurate ruler, so use it!

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